

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE  
LITIGATION

*This document relates to:  
Track One Cases*

MDL 2804

Case No. 17-md-2804

Hon. Dan Aaron Polster

Mag. Judge David A. Ruiz

**PEC'S RESPONSE TO DISTRIBUTOR AND PHARMACY DEFENDANTS'  
PARTIAL OBJECTION TO DISCOVERY RULING NO. 7**

The Defendants' objection to Decision Ruling No. 7 ("DR7") is actually a continued attempt to avoid their **own** discovery obligations. Specifically, Defendants have a legal obligation under federal law to design and operate a Suspicious Order Monitoring System ("SOMS"), and an obligation to disclose their SOMS to the Plaintiffs in discovery. As discussed below, however, Defendants have not done so. Instead, they insist that **Plaintiffs** must tell **them** which Orders were suspicious. Until Defendants explain how their own SOMS work, and what investigations they undertook when their own SOMS identified a suspicious order, Plaintiffs can only estimate which orders were suspicious using several possible rules. That is what Plaintiffs did in their discovery response to Defendants, and Plaintiffs will refine their answer after their experts have a chance to review all of the relevant information (including the SOMS, if Defendants ever produce them).

Defendants' objection, seeking to prevent Plaintiffs' experts from rendering opinions that Plaintiffs cannot now predict, is directly contrary to Case Management Order No. 7. CMO 7 provides that Plaintiffs must disclose their expert reports by February 8, 2019. To preclude Plaintiffs from formulating contentions based on the opinions to be rendered by those experts at that time would render the deadline for expert reports, and the orderly progression of discovery in this case, a nullity. Whether or not Defendants are entitled now to Plaintiffs' interim contentions, Plaintiffs are entitled to the benefit of their experts' opinions in formulating their ultimate contentions for trial. Until Plaintiffs' experts have had a chance to render their opinions, the Defendants' objection to DR7 is entirely inappropriate, and Plaintiffs' response is sufficient.

In support of the summary explanation provided above, Plaintiffs further state:

1. Federal law mandates that each distributor of controlled substances must "design and operate a system" to identify "suspicious orders" which is commonly referred to as the "**Security Requirement.**"<sup>1</sup> The PEC faces many obstacles in creating a record of how each "system" was designed and operated by each Distributor.

2. These systems employ "sophisticated software" which is "based on a **computer algorithm**" which "was meant to be used to calculate the quantity which, if exceeded in one month, constituted an order which may be considered excessive or suspicious."<sup>2</sup> These systems were designed by statisticians, consultants, third-party vendors and lawyers.

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<sup>1</sup> Federal law imposes three legal duties: (1) a Security Requirement; (2) a Reporting Requirement; and (3) a [Do Not] Shipping Requirement. 21 C.F.R. § 1301.74(b) [1971]; *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206, 212–13 (D.C. Cir. 2017) (emphasis added). There is a legal dispute whether the ruling in *Masters* is retroactive. Resolution of this legal issue may be dispositive of liability for some of the distributors. The PEC believes this issue may be ripe for consideration.

<sup>2</sup> See Correspondence from Enu Mainigi (counsel for Cardinal Health) to Alan Slobodin, Esq., Chief Counsel for Oversight and Investigations United States House of Representatives Committee on Energy and

3. The PEC served discovery demanding disclosure of the system each Distributor “designed and operated” including:

Please produce each of your **Suspicious Order Monitoring System (SOMS)** policies and procedures since January 1, 2006 and identify the Bates stamp range for each; please identify the effective date(s) each was in force and effect.

Request No. 2, *Plaintiffs (First) Combined Discovery Requests To Distributor Defendants* (served on July 1, 2018). The PEC specifically asked each of the Distributors to disclose **“any metrics, tools, models, workflows, platforms, computer program[s] and/or protocol[s] used or utilized”** in its Suspicious Order Monitoring System (SOM). See e.g., Request 24(d) of *Plaintiffs’ First Set Of Requests For Production of Documents To Cardinal Health, Inc.* The PEC also sought this evidence through Rule 30(b)(6) of the Federal Rules of Civil Procedure by requesting the designation of a corporate witness on the following subject matters:

- ☐ Your past/present policies, procedures, programs, standards and metrics related to due diligence following the detection of a suspicious order;
- ☐ Your past/present policies, procedures, programs, standards and metrics used to identify orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency; and
- ☐ How Your policies, procedures, programs, standards and metrics used to identify suspicious orders has changed over time.

See *First Notice Of Deposition Pursuant To Rule 30(B)(6) And Document Request Pursuant To Rule 30(B)(2) And Rule 34 To Defendant Amerisourcebergen Drug Corporation*, ¶ III(h)(i) and (j).

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Commerce, dated April 25, 2018. This document, like nearly every other document disclosed by Cardinal Health, has been designated as “confidential.” A bench copy of all exhibits referenced herein in lieu of filing under seal will be provided.

4. None of the Distributors have provided complete responses sufficient to identify and accurately apply each Distributor's algorithm to their own transactional data.

The Distributors have avoided disclosure by:

- a. Objecting to disclosure of any system parameters prior to 2006;
- b. Referencing a broad range of policy and procedure documents;
- c. Referring to third-party vendors, without producing documents, and then invoking attorney-client privilege and/or work product to avoiding producing the vendors' documents;
- d. Cloaking regulatory compliance and audits with attorney-client privilege;
- e. Claiming the documents no longer exist; and
- f. Providing evasive and non-responsive answers during depositions.

5. The PEC met and conferred with the Distributors on each of these deficiencies and triggered the process set forth in the case management order with the discovery special master.

6. In the meantime, SM Cohen ordered the PEC to respond to a contention interrogatory and identify all suspicious orders we contend the distributors failed to report and/or shipped without performing due diligence. In the absence of knowing the algorithm adopted by each distributor, the PEC applied the standard set forth in the *Masters* case and other logical metrics that a reasonable and prudent distributor could have applied. To be clear, the PEC understands the Security Requirement mandates that each Distributor apply its own standard, so long as that standard is sufficient to detect, report, and stop shipment of suspicious orders. The record is simply incomplete to do so. The PEC suspects the reason each "system" has not been disclosed is because there are significant

deficiencies in each Distributor's history. The PEC has done its best to outline and describe what it contends is the factual basis for its claims based upon the current record. We will continue to supplement our response as discovery proceeds and will disclose expert opinion testimony consistent with the scheduling order entered by the Court.

7. The PEC notes the irony of the Distributors' argument. It is they that have the duty to "design and operate a system" to disclose suspicious orders. Nonetheless, the PEC has met the challenge of the contention interrogatory by applying "a rule" described by the *Masters* Court as "common sense" and premised upon the "plain language" of the federal regulation, and other common sense criteria.

8. Having responded to the contention interrogatory by identifying thousands of suspicious orders in the CT1 bellwethers that Distributors should have investigated and reported and, if appropriate, rejected, the PEC now demands the Distributors certify for the record each system it designed and operated (between 1996 and the present) in satisfaction of the Security Requirement. The PEC asks the Court to take judicial notice that failure to do so will result in a rebuttable presumption that no such system was designed and/or was operational. (Alternatively, the PEC will file a motion asking for a ruling that, absent production of SOMS by a date certain, there will be an irrebuttable presumption that the SOMS did not exist.)

9. Moreover, the objection lodged by the Distributors should be denied as an impermissible attempt to limit the PEC's expert witness testimony and delay these proceedings. A party must disclose expert testimony "at the times and in the sequence that the court orders." Fed. R. Civ. P. 26(a)(2)(D). As noted above, CMO 7 sets February 8, 2019, as the deadline for Plaintiffs' disclosure of their experts' opinions. What

constitutes an appropriate system for monitoring suspicious orders is clearly an appropriate topic for expert opinion. By seeking to preclude Plaintiffs' experts from using different criteria for suspicious orders than those used by Plaintiffs now, Defendants seek to deprive Plaintiffs of the meaningful use of expert opinions on that subject. They seek to bind Plaintiffs to a set of criteria before Plaintiffs have had the opportunity to obtain the views of their experts. Such an approach would clearly undermine the schedule of discovery established by this Court, which sequences fact and expert discovery in an orderly fashion.

10. Nor are parties bound to answers to interrogatories in any event. As the Advisory Committee explained in connection with the amendment of Rule 33 to allow for contention interrogatories, "[t]he general rule governing the use of answers to interrogatories is that under ordinary circumstances they do not limit proof." Advisory Committee Note, Fed. R. Civ. P. 33(b) (1970). The Advisory Committee further stated that "the interrogating party will ordinarily not be entitled to rely on the unchanging character of the answers he receives" and that "[t]he rule does not affect the power of a court to permit withdrawal or amendment of answers to interrogatories." *Id.* Indeed, it was precisely because interrogatory answers are *not* binding that the Advisory Committee believed that allowing for contention interrogatories would work no mischief. *Id.* (rejecting concerns that contention interrogatories would cause parties to be "chained to misconceived contentions or theories" because the answers are not binding).

11. Moreover, the non-binding nature of interrogatory answers is simply an elaboration of the general rule permitting, indeed requiring, a party to supplement its interrogatory answers "if the party learns that in some material respect the disclosure or

response is incomplete or incorrect.” Fed. R. Civ. P. 26(e)(1). Defendants’ objection asks this Court to deny Plaintiffs the opportunity to supplement their answers based on new information in the form of opinions from their experts, even though such supplementation is clearly permissible under the Federal Rules.

12. Defendants’ argument that they must be able to tell “whether they are aiming at the duck or a decoy,” see Objection at 6, is an extraordinary example of over-reaching, and misapprehends the nature of discovery. Defendants’ Objection amounts to an argument that Plaintiffs must be bound to a specific view of the case early in the discovery process so that Defendants will know precisely the contentions to which they must respond. But the discovery process does not exist solely to allow Defendants to prepare their defense; Plaintiffs, too, must be given the benefit of discovery in order to formulate their case, and should not be prematurely bound to an early view of the case. Under CMO 7, Defendants will have more than six weeks following receipt of Plaintiffs’ expert reports to have their own experts respond to Plaintiffs’ criteria and identification of suspicious orders. They will have many months after that to use the actual information in their possession to formulate their challenge Plaintiffs’ contentions. The Court should not bind Plaintiffs to interim contentions formed, at Defendants’ demand, before the close of discovery and before Plaintiffs’ experts have had an opportunity to render their opinions.

13. Finally, Plaintiffs note that the interrogatories in question seek trial contentions that many courts believe need not be provided until the close of discovery. *Schweinfurth v. Motorola, Inc.*, No. 1:05CV0024, 2007 WL 6025288, at \*4 (N.D. Ohio Dec. 3, 2007) (“There is considerable authority for the view that the wisest general policy is to defer propounding and answering contention interrogatories until near the end of the

discovery period.”), *aff’d as modified*, No. 1:05CV024, 2009 WL 349163 (N.D. Ohio Jan. 26, 2009); *see also Francis v. Lakewood Eng’g & Mfg. Co.*, No. 05-2429 MAV, 2006 WL 8434945, at \*2 (W.D. Tenn. July 18, 2006) (noting trend of deferring answers to contention interrogatories and citing cases); *Nestle Foods Corp. v. Aetna Cas. & Sur. Co.*, 135 F.R.D. 101, 110–11 (D.N.J. 1990) (“[J]udicial economy as well as efficiency for the litigants dictate that contention interrogatories are more appropriate after a substantial amount of discovery has been conducted.”); *Civolution B.V. v. Doremi Labs, Inc.*, No. LACV1400962-JAK(RZx), 2015 WL 11072167, at \*1 (C.D. Cal. June 11, 2015) (“answers to contention interrogatories evolve over time as theories of liability and defense begin to take shape; answers to those interrogatories may not come into focus until the end of discovery.”). In the face of Plaintiffs’ arguments that the issue was a matter of expert opinion, the Special Master decided to give the Defendants an early view of Plaintiffs’ contentions, rather than requiring them to wait until receiving Plaintiffs’ expert reports, but to make clear that Plaintiffs’ experts would still have an opportunity to offer their own, independent opinions. Not content with a preliminary response they might have been denied altogether, Defendants seek, in their Objection, to bind Plaintiffs to that response. This turns Discovery Ruling 7 on its head: without the expert proviso, there would be no justification for the underlying ruling, which would improperly deprive Plaintiffs of the benefits of discovery. The Objection should be rejected in its entirety.



Dated: November 19, 2018

Respectfully submitted,

s/ Paul T. Farrell, Jr.

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### **CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that on this 19th day of November, 2018, I electronically filed the foregoing with the Clerk of Court by using the CM/ECF System. Copies will be served upon counsel of record by, and may be obtained through, the Court CM/ECF System.

s/Peter H. Weinberger

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